Remarks

A. Pending Claims

Claims 1-12, 29-70, 74-95, 99-140, 146-154, 157-165, and 168-245 are currently pending. Claims 13, 14, 71-73, 96-98, 141-145, 155-156, and 166-167 have been cancelled. Claims 1-12, 29-70, 74-95, 99-140, 146-154, 157-165, and 168-194 are rejected. Claims 1, 32-35, 43, 45, 48-49, 53, 74, 78, 99, 104, 114, 124, 138, 146, 157, 168-169, 176, 178, 185-187, and 194 have been amended. Claims 195-245 are new.

B. Double Patenting Rejection

The Office Action includes a provisional rejection of claims 1-12, 29-70, 74-95, 99-140, 146-154, 157-165, and 168-194 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,681,773 B2. Applicant respectfully disagrees that the rejection is appropriate; however to expedite prosecution of the current application Applicant has provided, as an attachment, a terminal disclaimer for the patent.

C. The Claims Are Definite Pursuant To 35 U.S.C. § 112, Second Paragraph

The Office Action includes a rejection of claims 1-12, 29-35, 45-47, 49-70, 74-95, 99-140, 146-154, and 157-165 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully disagrees with these rejections.

Definiteness is whether, in the light of the teachings of the prior art and of the particular invention, the claims set out and circumscribe a particular area with a reasonable degree of precision and particularity. *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236 (CCPA 1971).

Patent law does not require that all possible dimensions corresponding to hundreds of different variations be listed in the patent, let alone that they be listed in the claims. Claim language need only be as accurate as the subject matter permits. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986).

The Office Action states:

> It appears to this examiner that the claimed "size and shape of an appropriate left ventricle" limitation argued by applicant to be critical to patentability of the apparatus depends on not any specific parameters in the claims or specification, but rather on the size of some undefined patient[1], the size and shape a surgeon determines to be "appropriate" ... With such a position taken by applicant, the examiner is at a loss as to how anyone could possibly determine with any degree of objectivity whether a given balloon device meets the "size and shape of an appropriate left ventricle" limitation. This critical limitation (as applicant is interpreting it) fails to reasonably inform the public of what apparatuses fall within the bounds of the claim and which apparatuses do not.

Applicant submits the claims are definite when read in the light of the teachings of the prior art and of the particular invention.

Claim 1 describes a combination of features including: "a shaper having a size and shape substantially similar to the size and shape of an appropriate left ventricle, wherein the size of the appropriate left ventricle is less than the size of the enlarged left ventricle, wherein the shaper is adapted to be temporarily placed in the enlarged left ventricle during a surgical procedure." Claim 45 describes a combination of features including: "a shaper having a size and shape which

substantially defines the size and shape of the appropriate left ventricle, wherein the shaper is to be placed in the enlarged left ventricle during a surgical procedure." Claim 49, 124, and 138 describe a combination of features including: "wherein the shaper comprises a predetermined shape, wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use." Claim 74 describes a combination of features including: "wherein the shaper comprises a predetermined shape, wherein the predetermined shape is different than a geometry of the left ventricle, wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use." Claims 99, 104, and 114 describe a combination of features including: "wherein the shaper is configurable to expand to a predetermined shape during use, wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use." Claim 146 describes a combination of features including: "a shaper having a size substantially similar to the size of an appropriate left ventricle of a human heart." Claim 157 describes a combination of features including: "a shaper having a shape substantially similar to the shape of an appropriate left ventricle of a human heart." Applicant submits the claims are definite when read in the light of the teachings of the prior art and of the particular invention.

For example, the specification states:

> **[0004]** The amount of blood pumped from the left ventricle divided by the amount of blood available to be pumped is referred to as the ejection fraction of the heart. Generally, the higher the ejection fraction the more healthy the heart. A normal heart, for example may have a total volume of one hundred milliliters and an ejection fraction of 60 percent. Under these circumstances, 60 milliliters of blood are pumped with each beat of the heart. It is this volume in the normal heart of this example that is pumped with each beat to provide nutrients including oxygen to the muscles and other tissues of the body.
> (Specification, page 2, paragraph 4).

The specification further states:

[0048] ... Turning now to Fig. 2a., there is shown a shaping device 200 that allows the left ventricle to be reconstructed back to a pre-enlarged operating condition. When the surgeon uses shaping device 200 as a guide in reconstructing the left ventricle, the reconstructed heart can be formed closer to the size and shape of the pre-enlarged heart. Consequently, the heart performs better post operatively than with conventional methods. As illustrated, the shaping device 200 is generally conical or "tear drop" in shape. The length "L" of the shaping device 200 may vary with each patient and will typically be a function of the volume selected for the shaping device. Depending on the patient, the length "L" may be in the three to four inch range to generally match the length of the pre-enlarged left ventricle. A surgeon may select the appropriate volume for the shaping device by estimating the volume of the pre-enlarged left ventricle. The appropriate volume of the pre-enlarged left ventricle for a patient may be estimated to be 50 to 70 cc per square meter of body surface area. The body surface area may be estimated according to the following formula; as known in the art:

$$BSA = 0.001*71.84w^{0.428}*h^{0.725}$$

Where: BSA = body surface area,
w = body weight in kilograms, and
h = body height in centimeters.

[0049] The shaping device may be of an "appropriate shape" for a patient. In other words, the shaping device may be of a shape similar to the shape of the left ventricle. In one embodiment, the shaping device 200 may be a generally conical shaped object composed of portions of spherical elements having different radii. Referring back to Fig. 2a, the illustrative embodiment of the shaping device may be divided lengthwise into six sections where each section is a length "L2" apart. L2, therefore, may be determined from the formula: L2 = .1665*L. At line "A-A", a width W1 of the shaping device 200 is approximately .543*L. The back surface 202 of the shaping device 200 is generally shaped as a portion of a sphere, having a radius of .802*L. At a line "C-C", a width W2 of the shaping device 200 is approximately .628*L. The side surfaces 204a and 204b are combinations of portions of spheres with different radii. Between the line A-A and the line C-C, the side surfaces 204a and 204b have a radius of .515L.

[0050] At a line "E-E", a width W3 of the shaping device 200 is .435*L. Between the line C-C and the line E-E, the side surfaces 204a and 204b have a radius of .945L. The shaping device 200 narrows from the line designated "E-E" through a line designated as "F-F" to a vertex 206 at point "G". It is important to

> note that the above discussion is illustrative of only one embodiment of the present invention and is not meant to limit the invention to the above ratios or shapes.

Applicant submits the specification teaches, through example, how a surgeon may determine the "size and shape of an appropriate left ventricle." Applicant submits patent law does not require that all possible dimensions corresponding to hundreds of different variations be listed in the patent, let alone that they be listed in the claims. Claim language need only be as accurate as the subject matter permits. Applicant submits it is well known to one skilled in the art how to determine an appropriate size and/or shape of a left ventricle.

The Office Action states, "Additionally, in claim 48, line 3, "sharper"?" Applicant has amended claim 48 to expedite prosecution of the present application.

The Office Action states there is no antecedent basis for "the viable tissue" in claims 176, 185, and 194. Applicant respectfully disagrees; however, to expedite prosecution of the present application Applicant has amended claims 176, 185, and 194 for purposes of clarity.

The Office Action states that dependent claims 174 and 176 would more logically follow from claim 170, dependent claims 183 and 185 would more logically follow from claim 179, and dependent claims 192 and 194 would more logically follow from claim 188. Applicant respectfully disagrees.

Applicant respectfully requests removal of the rejection of claims 1-12, 29-35, 45-47, 48, 49-70, 74-95, 99-140, 146-154, 157-165, 174, 176, 183, 185, 192, and 194.

D. The Claims Are Not Anticipated By Deslauriers Pursuant To 35 U.S.C. § 102(b)

The Office Action includes a rejection of claims 1-5, 8-12, 29-35, 45-47, 49, 50, 53-70, 74, 75, 78-95, 104-116, 119-138, 146-154, 157-165, 168, 169, 186, and 187 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,255,678 to Deslauriers et al. ("Deslauriers"). Applicant respectfully disagrees with these rejections.

The standard for "anticipation" is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed. Cir. 1986); In re Donahue, 766 F.2d 531,226 U.S.P.Q. 619,621 (Fed. Cir. 1985).

The Office Action states:

> Deslauriers et al disclose a balloon device 20 shaped and sized to be fitted within the left ventricle when inflated. The device further includes a tube 23 in fluid communication with the balloon 20, a valve 24, pressure gauge (column 8, line 65) and syringe 26. The purpose for which applicant intends the device to be used (i.e. a "shaper") fails to impose any objectively ascertainable structural distinctions from the device disclosed by Deslauriers et al.

Applicant respectfully disagrees that the purpose for which Applicant intends the device to be used fails to impose any objectively ascertainable structural distinctions from the device disclosed by Deslauriers.

Claim 1 describes a combination of features including: "a shaper having a size and shape substantially similar to the size and shape of an appropriate left ventricle, wherein the size of the appropriate left ventricle is less than the size of the enlarged left ventricle, wherein the shaper is adapted to be temporarily placed in the enlarged left ventricle during a surgical procedure."

Claim 45 describes a combination of features including: "a shaper having a size and shape which substantially defines the size and shape of the appropriate left ventricle, wherein the shaper is to be placed in the enlarged left ventricle during a surgical procedure." Claims 49, 124, and 138 describe a combination of features including: "wherein the shaper comprises a predetermined shape, wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use." Claim 74 describes a combination of features including: "wherein the shaper comprises a predetermined shape, wherein the predetermined shape is different than a geometry of the left ventricle, wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use." Claims 104, and 114 describe a combination of features including: "wherein the shaper is configurable to expand to a predetermined shape during use, wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use." Claim 146 describes a combination of features including: "a shaper having a size substantially similar to the size of an appropriate left ventricle of a human heart." Claim 157 describes a combination of features including: "a shaper having a shape substantially similar to the shape of an appropriate left ventricle of a human heart."

Deslauriers discloses:

> Second, the form of the balloon is determined based on the cut-out of the knitting and on its assembly. This way, the balloon conforms with the cavity for which it is intended. Balloons of proper shapes can thus be obtained for the ventricles or the auricles of both animals or humans, normal or diseased.
>
> Third, the volume of the electrode balloon adjusts itself to the variability of the cardiac cavities which are encountered from one patient to another. More or less inflated, the balloon offers a wide enough range of functional volumes within which the deployment of the electrodes is regular and reproducible.
> (Deslauriers, column 17, lines 37-48).

Deslauriers further discloses:

> It is still a further aim of the present invention to provide a knitting for a particular one of the cardiac chambers which has a pattern adapted to confer to the electrode balloon a shape that will allow the same to contact when expanded the inner wall of the cardiac chamber for various volumes and shapes of the latter. (Deslauriers, column 4, lines 32-37).

Deslauriers appears to teach or suggest a balloon capable of expanding to fill various sized chambers of a heart so that a knitted pattern of electrodes covering the balloon will make contact with the interior surface of the heart chamber. Deslauriers appears to specifically teach balloons which conform to fit any cavity including diseased cavities of a heart. Deslauriers appears to teach that for Deslauriers' invention to function as intended electrodes positioned on Deslauriers' balloon must be evenly distributed around cardiac cavity and contacting the interior surface of the cardiac cavity. Deslauriers does not appear to teach or suggest a shaper of substantially equal size and/or shape of an appropriate left ventricle (e.g., wherein the appropriate left ventricle is smaller than an enlarged left ventricle) configurable to assist in reconstructing an enlarged left ventricle.

Deslauriers appears to teach away from the claimed invention of the present application because Deslauriers teaches that his balloon completely fills a cavity in which the balloon is placed. The present application, however, teaches a shaper configured to assume a size and/or shape of an appropriate left ventricle (e.g., wherein the appropriate left ventricle is smaller than an enlarged left ventricle).

In addition, claims 1, 45, 146, and 157 describe a combination of features including: "wherein the shaper is configured such that, when temporarily placed in the enlarged left ventricle during a surgical procedure, the shaper exhibits sufficient firmness such that the shaper can be used as a model to reconstruct the enlarged left ventricle." Claims 49, 74, 104, 114, 124, and 138 describe a combination of features including: "wherein the shaper is configured such

that, when temporarily placed in the left ventricle during a surgical procedure, the shaper exhibits sufficient firmness such that the shaper can be used as a model to reconstruct the left ventricle." Applicant submits that the amendments add no new matter.

The shaper exhibiting sufficient "firmness" to be used as a model for reconstruction is a feature of the shaper as described in the present application. Firmness is a feature of the shaper for the shaper to be able to function as a model for left ventricular reconstruction. Firmness is the noun form of "firm" and is generally defined as "resistant to externally applied pressure" (*The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000 by Houghton Mifflin Company. Published by Houghton Mifflin Company*). Support for amendments to claims 1, 45, 49, 74, 104, 114, 124, 138, 146, and 157 may be found at least in Figure 1 and Figure 7a as regards reference number 118 and 720 respectively, which recite, "RECONSTRUCT LEFT VENTRICLE USING SHAPING DEVICE." In addition Figure 7a as regards reference number 722 recites, "TIGHTEN FONTAN SUTURES." The specification provides support at least on page 22 in paragraph [0090]:

> The shaping device 200 provides the model upon which the ventricle can be shaped and contoured through the use of the Fontan suture in step 720. The Fontan suture may then tightened with the aid of the suture hook 520, in step 722. As the suture or sutures are tightened, the musculature of the myocardium will form the physiologically correct volume, shape and contour over the shaping device. The appropriately oval-shaped opening in the neck defines the area where the patch will be placed. Once the suture is tightened down, the shaping device 200 may be collapsed and removed in step 724.

For the shaper to function as a model during a left ventricular reconstruction as described above the shaper exhibits sufficient firmness to resist externally applied pressure, such as, for example, when the Fontan sutures are tightened with the aid of a suture hook to "form the physiologically correct volume, shape and contour over the shaping device." Many of the examples in the present application refer to an inflatable shaper; however a shaper may include a solid shaper.

The solid shaper may be formed from various materials known to one skilled in the art (e.g., rubber, foam or plastic). The shaper may also in some embodiments be hollow.

As demonstrated in the quotes from Deslauriers recited herein, Deslauriers appears to teach or suggest a balloon capable of expanding to fill various sized chambers of a heart so that a knitted pattern of electrodes covering the balloon will make contact with the interior surface of the heart chamber. Deslauriers appears to specifically teach balloons which conform to fit any cavity including diseased cavities of a heart. Balloons that are pliable enough to conform to fit any cavity of a heart cannot possess the firmness required to act as a model during ventricular reconstruction.

A declaration under 37 C.F.R. §1.132 of an inventor of the present application is provided for further support hereof. The declarant, Mitta Suresh, has worked on cardiovascular products for over twelve years. He is knowledgeable about devices used for left ventricular reconstruction. Mr. Suresh states (at paragraph 7):

> Based on my review of Deslauriers, and my education and experience, it is my opinion that the devices set forth in Deslauriers cannot be used as a model for left ventricular reconstruction. The devices set forth in Deslauriers are designed for a different purpose, namely, providing a balloon which "conforms with the cavity for which it is intended" as well as "picking up bioelectrical signals from the walls of anatomical cavities simultaneously in a multitude of sites for the mapping of activation potentials thereof." In my opinion the devices set forth in Deslauriers do not have sufficient firmness to allow such devices to be used as a model for left ventricular reconstruction.

Based on the above, Applicant submits Deslauriers does not appear to teach all of the

features in claims 1, 45, 49, 74, 104, 114, 124, 138, 146, and 157 and the claims dependent thereon.

The Office Action states: "In regard to claims 168 and 169, note column 13, lines 25-28, where the left ventricle is reshaped to conform to the shape of the balloon." Applicant respectfully disagrees with this statement.

Claim 168 describes a combination of features including: "reshaping at least a portion of the left ventricle about the shaper such that at least a portion of the left ventricle substantially conforms to a predetermined shape of the shaper." Claim 186 describes a combination of features including: "reshaping at least a portion of the left ventricle about the shaper such that at least a portion of the left ventricle substantially conforms to the predetermined shape of the shaper." Claim 169 describes a combination of features including: "wherein at least a portion of the left ventricle substantially corresponds to the predetermined shape of the shaper."

Deslauriers only discloses:

> The cutting of the knitting 10 and its assembly determines the shape and the maximum volume of the inflated balloon 20 intended therefor. The balloon 20 is dimensioned to obtain an electrode distribution which is regular, predictable and reproducible as well as a proper contact of all of its electrodes 12 on the cardiac surfaces being studied.
>
> However, it is noted that the balloon takes its shape and that the cardiac muscle, in view of its suppleness, adjusts itself thereto, to a certain degree. This provides a certain maneuverability margin.
> (Deslauriers, column 13, lines 18-28).

Thus Deslauriers appears to teach a balloon which is assembled to conform to a cardiac surface to be studied, and any adjustment of the cardiac muscle, in view of its suppleness, to the shape of the balloon is minor. Deslauriers does not appear to teach a method comprising reshaping at

least a portion of the left ventricle about the shaper such that at least a portion of the left ventricle substantially conforms to the predetermined shape of the shaper wherein the shaper comprises a shape and/or size different from the enlarged left ventricle. Applicant submits Deslauriers does not appear to teach all of the features in claims 168 and 186 and the claims dependent thereon. Applicant submits that many of the claims dependent on claims 1, 45, 49, 74, 104, 114, 124, 138, 157, 168, and 186 are separately patentable.

Applicant respectfully requests removal of the rejection of claims 1-5, 8-12, 29-35, 45-47, 49, 50, 53-70, 74, 75, 78-95, 104-116, 119-138, 146-154, 157-165, 168, 169, 186, and 187.

E. The Claims Are Not Anticipated By Dor Pursuant To 35 U.S.C. § 102(b)

The Office Action included a rejection of claims 1, 2, 36, 43, 45-46, 48-50, 53-58, 64-65, 74-75, 78-83, 86, 90, 146-149, 153, 157-160, 164, 168-169, and 186-187 under 35 U.S.C. 102(b) as anticipated by "Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg. 199:14:46-52) to V. Dor et al ("Dor"). Applicant respectfully disagrees with these rejections.

The Office Action states:

> Note Figure 2 and the second column of page 48 which discloses the repair of a patient's heart wherein an appropriately shaped balloon is inserted into the patient's left ventricle and inflated to the appropriate size (volume) and then deflated and removed once the left ventricle has been appropriately shaped.

Applicant respectfully disagrees that Dor anticipates the invention as claimed by Applicant.

Claim 1 describes a combination of features including: "a shaper having a size and shape

substantially similar to the size and shape of an appropriate left ventricle, wherein the size of the appropriate left ventricle is less than the size of the enlarged left ventricle, wherein the shaper is adapted to be temporarily placed in the enlarged left ventricle during a surgical procedure." Claim 45 describes a combination of features including: "a shaper having a size and shape which substantially defines the size and shape of the appropriate left ventricle, wherein the shaper is to be placed in the enlarged left ventricle during a surgical procedure." Claim 48 describes a combination of features including: "placing a shaper into the enlarged left ventricle, the shaper having a size and shape substantially equal to the size and shape of an appropriate left ventricle, reforming the enlarged left ventricle over the shaper." Claim 49 describes a combination of features including: "wherein the shaper comprises a predetermined shape, wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use." Claim 74 describes a combination of features including: "wherein the shaper comprises a predetermined shape, wherein the predetermined shape is different than a geometry of the left ventricle, wherein the predetermined shape acts as a pattern to reconstruct the left ventricle about the shaper during use." Claim 146 describes a combination of features including: "a shaper having a size substantially similar to the size of an appropriate left ventricle of a human heart." Claim 157 describes a combination of features including: "a shaper having a shape substantially similar to the shape of an appropriate left ventricle of a human heart." Claim 168 describes a combination of features including: "reshaping at least a portion of the left ventricle about the shaper such that at least a portion of the left ventricle substantially conforms to a predetermined shape of the shaper." Claim 186 describes a combination of features including: "reshaping at least a portion of the left ventricle about the shaper such that at least a portion of the left ventricle substantially conforms to the predetermined shape of the shaper."

Dor discloses:

> This avoids limiting of the diastolic volume. To check the new LV

> diastolic volume, a small rubber balloon is inflated (Fig. 2B) within the ventricle (theoretical volume between 50 and 70 cc per square meter of body surface).... Then the balloon is evacuated and removed. The diameter of the intraventricular suture give the size of the patch, which is tailored 1-cm larger.
> (Dor, page 48, column 2, lines 1-9).

Dor appears to teach using a balloon to check the new left ventricular diastolic volume. Dor does not appear to teach using the balloon during the reconstruction of the left ventricle to reshape the left ventricle using a balloon with a predetermined shape. Dor does not appear to teach a method comprising reshaping at least a portion of the left ventricle about the shaper such that at least a portion of the left ventricle substantially conforms to the predetermined shape of the shaper wherein the shaper comprises a shape and/or size different from the enlarged left ventricle. Dor appears to teach away from the claimed invention of the present application merely using his balloon to check the volume of a reconstructed ventricle, the present application teaches a shaper configured to assume a size and/or shape of an appropriate left ventricle (e.g., wherein the appropriate left ventricle is smaller than an enlarged left ventricle) for use as a model for reconstructing a ventricle about.

In addition, claims 1, 45, 146, and 157 describes a combination of features including: "wherein the shaper is configured such that, when temporarily placed in the enlarged left ventricle during a surgical procedure, the shaper exhibits sufficient firmness such that the shaper can be used as a model to reconstruct the enlarged left ventricle." Claims 49 and 74 describes a combination of features including: "wherein the shaper is configured such that, when temporarily placed in the left ventricle during a surgical procedure, the shaper exhibits sufficient firmness such that the shaper can be used as a model to reconstruct the left ventricle." For the shaper to function as a model during a left ventricular reconstruction as described in the present application the shaper exhibits sufficient firmness to resist externally applied pressure, such as, for example, when the Fontan sutures are tightened with the aid of a suture hook to "form the physiologically correct volume, shape and contour over the shaping device."

As demonstrated in the quotes from Dor recited herein, Dor appears to teach using a balloon to check the new left ventricular diastolic volume. Balloons that are pliable enough to conform to fit a cavity of a heart to determines the cavities volume cannot inherently possess the firmness required to act as a model during ventricular reconstruction.

A declaration under 37 C.F.R. §1.132 of an inventor of the present application is provided for further support hereof. The declarant, Mitta Suresh, has worked on cardiovascular products for over twelve years. He is knowledgeable about devices used for left ventricular reconstruction. Mr. Suresh states (at paragraph 5):

> Based on my review of Dor, and my education and experience, it is my opinion that the devices set forth in Dor cannot be used as a model for left ventricular reconstruction. The devices set forth in Dor are designed for a different purpose, namely, to "check the new LV diastolic volume." In my opinion the devices set forth in Dor do not have sufficient firmness to allow such devices to be used as a model for left ventricular reconstruction.

Based on the above, Applicant submits Dor does not appear to teach all of the features in claims 1, 45, 48, 49, 74, 146, 157, 168, and 186 and the claims dependent thereon. Applicant submits that many of the claims dependent on claims 1, 45, 48, 49, 74, 146, 157, 168, and 186 are separately patentable.

Applicant respectfully requests removal of the rejection of claims 1, 2, 36, 43, 45-46, 48-50, 53-58, 64-65, 74-75, 78-83, 86, 90, 146-149, 153, 157-160, 164, 168-169, and 186-187.

F. The Claims Are Not Obvious over Deslauriers in View of Hillegass, Kovacs, and Cook Pursuant To 35 U.S.C. § 103(a)

The Office Action includes rejections of claims 6, 7, 57, 58, 82, 83, 99-103, 108, 109, 117, 118, 131, 132, 177, and 178 under 35 U.S.C. 103(a) as obvious over Deslauriers in view of U.S. Patent No. 4,817,637 to Hillegass et al. ("Hillegass"), U.S. Patent No. 5,749,839 to Kovacs ("Kovacs"), and U.S. Patent No. 5,964,806 to Cook et al ("Cook"). Applicant respectfully disagrees with these rejections.

The Office Action states:

> Deslauriers et al indicates that the balloon member is filled with a saline solution rather than the claimed silicone gel. The prior art, however, is replete with teachings that silicone gel may conventionally be used in place of saline for inflating medical balloon devices as is evidenced for example by Hillegass et al (column 3, lines 59-60), Kovacs (column 3, line 61) and Cook et al (column 3, lines 49-53). To have selected silicone gel rather than saline for the balloon inflation fluid as is well known in the art would have been obvious to the ordinary skilled artisan. In regards to claims 57, 58, 82, 83, 108, 109, 131, and 132, to the extent that one interprets the fluid to be positively claimed, the present rejection applies.

For at least the reasons in Section D above, Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 6, 7, 57, 58, 82, 83, 99-103, 108, 109, 117, 118, 131, 132, 177, and 178. Applicant respectfully submits that the cited art does not teach or suggest, for example, the features of these claims in shapers used in ventricular reconstruction. Support for amendments to claim 99 are also outlined in Section D.

Applicant requests removal of the obviousness rejection of claims 6, 7, 57, 58, 82, 83, 99-103, 108, 109, 117, 118, 131, 132, 177, and 178.

G. The Claims Are Not Obvious over Deslauriers Pursuant To 35 U.S.C. § 103(a)

The Office Action includes a rejection of claims 51, 52, 76, and 77 under 35 U.S.C. 103(a) as obvious over Deslauriers. Applicant respectfully disagrees with these rejections.

The Office Action states:

> One of ordinary skill in the art would have found the manufacture of the Deslauriers et al device with the particular thickness dimension claimed obvious as a matter of routine.

For at least the reasons in Section D above, Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 51, 52, 76, and 77. Applicant respectfully submits that the cited art does not teach or suggest, for example, the features of these claims in shapers used in ventricular reconstruction. Applicant requests removal of the obviousness rejection of claims 51, 52, 76, and 77.

H. The Claims Are Not Obvious over Dor Pursuant To 35 U.S.C. § 103(a)

The Office Action includes a rejection of claims 3-5, 47, 51, 52, 59, 60, 76, 77, 84, 85, 150, 151, 161, and 162 under 35 U.S.C. 103(a) as obvious over Dor. Claims 146-156 have been cancelled. Applicant respectfully disagrees with these rejections.

The Office Action states:

> V. Dor et al fail to disclose that the balloon once fully inflated that it cannot be substantially further expanded or that the balloon maintains its shape while being inflated, however, one of ordinary skill in the art would have found

such limitations obvious in the design and construction of the disclosed balloon. The ordinarily skilled artisan would have been motivated to use a balloon that resisted further filling once full so as to not provide for too large of a size during the V. Dor et al procedure and certainly the ordinarily skilled artisan would desire a balloon that maintained it shape during this critical open heart surgery. In regard to claims 51, 52, 76, and 77, the claimed wall thickness for the balloon fall well within a range one of ordinary skill in the art would have found to have been obvious in constructing the V. Dor et al balloon.

For at least the reasons in Section E above, Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 3-5, 47, 51, 52, 59, 60, 76, 77, 84, 85, 161, and 162. Applicant respectfully submits that the cited art does not teach or suggest, for example, the features of these claims in shapers used in ventricular reconstruction.

Applicant requests removal of the obviousness rejection of claims 3-5, 47, 51, 52, 59, 60, 76, 77, 84, 85, 161, and 162.

I. The Claims Are Not Obvious over Dor in View of Hillegass, Kovacs, and Cook Pursuant To 35 U.S.C. § 103(a)

The Office Action includes a rejection of claims 6, 7, 57, 58, 82, 83, 99, 100, 177, and 178 under 35 U.S.C. 103(a) as obvious over Dor in view of Hillegass, Kovacs, and Cook. Applicant respectfully disagrees with these rejections.

The Office Action states:

V. Dor et al fails to disclose what type of fluid is used to inflate the disclosed balloon. The prior art, however, is replete with teachings that silicone gel may conventionally be used for inflating medical balloon devices as is evidenced for example by Hillegass et al (column 3, lines 59-60), Kovacs (column 3, line 61) and Cook et al (column 3, lines 49-53). To have selected silicone gel

> for the balloon inflation fluid as is well known in the art would have been obvious to the ordinarily skilled artisan. In regard to claims 57, 58, 82, and 83, to the extent that one interprets the fluid to be positively claimed, the present rejection applies.

For at least the reasons in Section E above, Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 6, 7, 57, 58, 82, 83, 99, 100, 177, and 178. Applicant respectfully submits that the cited art does not teach or suggest, for example, the features of these claims in shapers used in ventricular reconstruction.

Applicant requests removal of the obviousness rejection of claims 6, 7, 57, 58, 82, 83, 99, 100, 177, and 178.

J. The Claims Are Not Obvious over Dor in View of Deslauriers Pursuant To 35 U.S.C. § 103(a)

The Office Action includes a rejection of claims 8-12, 32-35, 61-70, 87-89, 91-95, 152, 154, 163, and 165 under 35 U.S.C. 103(a) as obvious over Dor in view of Deslauriers. Claims 146-156 have been cancelled. Applicant respectfully disagrees with these rejections.

The Office Action states:

> In regard to claims 8-12, 61-63, 87-89, 152, and 163, V. Dor et al fail to disclose the specifically claimed structures in regard to the disclosed balloon. Deslauriers et al, however, for a similar balloon used in the left ventricle teaches that a tube for conveying the inflation fluid, the use of a valve, pressure gauge and syringe are all desirable for controlling the inflation of a left ventricle balloon. To have merely used such common prior art features for controlling the inflation of the V. Dor et al balloon would have been obvious to one of ordinary skill in the art. In regard to claims 32-35, 64, 66-70, 91-95, 154, and 165, V. Dor et al fail to disclose the actual shape of the disclosed balloon. Deslauriers et al, however,

> teaches that it is desirable to form left ventricle balloons in the shape of a left ventricle which may be either ellipsoidal shape as in Figure 9 or drop/pear/cone shaped as in Figure 10. To have shaped the V. Dor et al balloon so that it was the shape of the left ventricle as taught by Deslauriers et al would have been obvious to one of ordinary skill in the art.

Whether or not "a particular combination might be 'obvious to try' is not a legitimate test of patentability." *Id.* at 1599, citing *In re Geiqer*, 815 F.2d 868, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987) and *In re Goodwin*, 576 F.2d 375, 377, 198 USPQ 871, 881 (CCPA 1981). Consequently, it is not permissible for the Examiner to "use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." Id. at 1600.

In regards to Office Action's comments concerning "the actual shape of the disclosed balloon," Applicant submits that one skilled in the art would have no obvious motivations to combine the apparent teachings of Dor with the apparent teachings of Deslauriers. Dor appears to teach a procedure for reconstructing a left ventricle using a balloon to check the volume of a reconstructed left ventricle. Deslauriers appears to teach using an electrode balloon to study bioelectric signals, wherein electrodes from the balloon are in contact with the interior wall of a normal and/or enlarged cardiac chamber.

For at least the reasons in Sections D and E above, Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 8-12, 32-35, 61-70, 87-89, 91-95, 163, and 165. Applicant respectfully submits that the cited art does not teach or suggest, for example, the features of these claims in shapers used in ventricular reconstruction.

Applicant requests removal of the obviousness rejection of claims 8-12, 32-35, 61-70, 87-89, 91-95, 163, and 165.

K. The Claims Are Not Obvious over Dor in View of Hillegass, Kovacs, and Cook and in Further View of Deslauriers Pursuant To 35 U.S.C. § 103(a)

The Office Action includes a rejection of claims 101-103 under 35 U.S.C. 103(a) as obvious over Dor in view of Hillegass, Kovacs, and Cook and in further view of Deslauriers. Applicant respectfully disagrees with these rejections.

The Office Action states:

> V. Dor et al fail to disclose the specifically claimed structures in regard to the disclosed balloon. Deslauriers et al, however, for a similar balloon used in the left ventricle teaches that a tube for conveying the inflation fluid, the use of a valve, pressure gauge and a syringe are all desirable for controlling the inflation of a left ventricle balloon. To have merely used such common prior art features for controlling the inflation of the V. Dor et al balloon would have been obvious to one of ordinary skill in the art.

For at least the reasons in Sections D and E above, Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 101-103. Applicant respectfully submits that the cited art does not teach or suggest, for example, the features of these claims in shapers used in ventricular reconstruction.

Applicant requests removal of the obviousness rejection of claims 101-103.

L. Support for New Claims

Claims 195-245 are new. For at least the reasons outlined in Section D above, Applicant submits that there is sufficient support provided for the new claims. Applicant submits that the new claims add no new matter.

M. Conclusion

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

A fee authorization form is included to cover additional claims fees. If any extension of time is required, Applicant hereby requests the appropriate extension of time. If any additional fees are required, please appropriately charge, or credit, those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5838-00300/EBM.

Respectfully submitted,

Eric B. Meyertons
Reg. No. 34,876

Attorney for Applicant

MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.
P.O. BOX 398
AUSTIN, TX 78767-0398
(512) 853-8800 (voice)
(512) 853-8801 (facsimile)

Date: 5/19/04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 09/864,510
Confirmation No.: 2445
Filed: May 24, 2001
Inventor(s):
Murphy et al.

Title: VENTRICULAR RESTORATION SHAPING APPARATUS AND METHOD OF USE

§
§ Examiner: R. Lewis
§ Group/Art Unit: 3732
§ Old Atty. Dkt. No.: 28122.89
§ New Atty. Dkt. No.: 5838-00300
§
§
§
§
§
§
§
§
§

CERTIFICATE OF MAILING
UNDER 37 C.F.R. §1.8

DATE OF DEPOSIT: 5/19/04

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail on the date indicated above and is addressed to:
Commissioner for Patents
Alexandria, VA 22313-1450

Jackie L. Pitre

DECLARATION UNDER 37 C.F.R. §1.132 OF INVENTOR

I declare on the basis of personal knowledge as follows:

1. My name is Mitta Suresh (a.k.a. Suresh Reddy). I am a named inventor on the above-referenced patent application.

2. I have a graduate degree in mechanical engineering. I have worked on cardiovascular products for over twelve years. I am knowledgeable about devices used for left ventricular reconstruction.

3. I have reviewed "Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg. 199:14:46-52 to V. Dor et al. ("Dor"). I have reviewed U.S. Patent No. 5,255,678 to Deslauriers et al. ("Deslauriers").

4. Dor recites, in part:

> This avoids limiting of the diastolic volume. To check the new LV diastolic volume, a small rubber balloon is inflated (Fig. 2B) within the ventricle (theoretical volume between 50 and 70 cc per square meter of body surface). The endocardial suture is tied on this inflated balloon. Then the balloon is evacuated and removed. The diameter of the intraventricular suture give the size of the patch, which is tailored 1-cm larger. (Dor, page 48, column 2, lines 1-9).

5. Based on my review of Dor, and my education and experience, it is my opinion that the devices set forth in Dor cannot be used as a model for left ventricular reconstruction. The devices set forth in Dor are designed for a different purpose, namely, to "check the new LV diastolic volume." In my opinion the devices set forth in Dor do not have sufficient firmness to allow such devices to be used as a model for left ventricular reconstruction.

6. Deslauriers recites, in part:

> Second, the form of the balloon is determined based on the cut-out of the knitting and on its assembly. This way, the balloon conforms with the cavity for which it is intended. Balloons of proper shapes can thus be obtained for the ventricles or the auricles of both animals or humans, normal or diseased.
>
> Third, the volume of the electrode balloon adjusts itself to the variability of the cardiac cavities which are encountered from one patient to another. More or less inflated, the balloon offers a wide enough range of functional volumes within which the deployment of the electrodes is regular and reproducible. (Deslauriers, column 17, lines 37-48).

Deslauriers further recites:

> It is still a further aim of the present invention to provide a knitting for a particular one of the cardiac chambers which has a pattern adapted to confer to the electrode balloon a shape that will allow the same to contact when expanded the inner wall of the cardiac chamber for various volumes and shapes of the latter. (Deslauriers, column 4, lines 32-37).

7. Based on my review of Deslauriers, and my education and experience, it is my opinion that the devices set forth in Deslauriers cannot be used as a model for left

ventricular reconstruction. The devices set forth in Deslauriers are designed for a different purpose, namely, providing a balloon which "conforms with the cavity for which it is intended" as well as "picking up bioelectrical signals from the walls of anatomical cavities simultaneously in a multitude of sites for the mapping of activation potentials thereof." In my opinion the devices set forth in Deslauriers do not have sufficient firmness to allow such devices to be used as a model for left ventricular reconstruction.

I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or of any patent issued thereon.

Name:(printed or typed) Mitta Suresh

Signature: _____

Date: April 19th 2004